



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95145d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-15

December 21, 2004

Lawrence A. Borawski
188 Cays Drive
Naples, Florida 34114

Dear Mr. Borawski:

The Food and Drug Administration (FDA) has reviewed your website at the Internet address <http://store.yahoo.com/carboblock> and has concluded that claims on this website cause your products Ultra Carbo Blocker 2000, Ultra Block 2000 Plus C, and Slender Quick 2000 to be misbranded under provisions of the Federal Food, Drug, and Cosmetic Act (the Act). Furthermore, website claims for your products MSM 2000 Plus C, Ultra Carbo Blocker 2000, and Slender Quick 2000 represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease. Such claims cause these products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Specifically, the Internet labeling of MSM 2000 Plus C, Ultra Carbo Blocker 2000 and Slender Quick 2000 bears disease claims that include the following:

- MSM 2000 Plus C
 - "Great for Arthritis"
 - "Discover relief from arthritis pain"
 - "Individuals presenting ...pain and inflammation associated with various musculoskeletal system disorders reported substantial and long lasting relief Migraine sufferers have obtained substantial relief with MSM."
 - "Reduction of hypertension" [listed under heading "PATENTED BENEFITS OF MSM"]
 - "MSM has an ameliorating (alleviating) or curing effect on a variety of parasitic systemic microbial infections."

- Ultra Carbo Blocker 2000:
 - "Gymnema Sylvestre [an ingredient in the product] ...is a plant used medicinally ...for treatment of diabetes and hyperglycemia."
 - "Gymnema sylvestre has been clinically proven to reduce blood sugar and cholesterol levels in diabetic animals and humans...."
 - Testimonial: "Since I am diabetic, I have also been able to reduce my insulin intake due to lower blood sugar. With improved blood sugar values, I'm in better control of my diabetes."
- Slender Quick 2000
 - "The extract [of Garcinia Cambogia, an ingredient in the product] is effective in treating obesity, [and] for reducing cholesterol...."

Based on the claims noted above, these products are drugs under the Act since they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man [Section 201(g)(1)(B) of the Act]. Because the products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Furthermore, MSM 2000 Plus C, Ultra Carbo Blocker 2000, and Slender Quick 2000 are misbranded under section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use for the conditions for which they are offered.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met [21 U.S.C. § 343(r)(6)(A)]. One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading [21 U.S.C. § 343(r)(6)(B)].

Even if the Internet labeling of your products Ultra Carbo Blocker 2000 and Slender Quick 2000 did not contain disease claims that cause these products to be drugs, the unsubstantiated structure/function claims on your website would misbrand these products as dietary supplements. In addition, your website makes unsubstantiated structure/function claims for the product Ultra Block 2000 Plus C, which is labeled and marketed as a dietary supplement. Examples of unsubstantiated structure/function claims for these products on your website include the following:

- Ultra Carbo Blocker 2000:
 - "[U]sing this product just before eating may help reduce the absorption of carbohydrate/starch calories."

- "Chromium Polynicotinate [an ingredient in the product] ...was also shown to decrease body fat by 22% in one study."
 - "[D]ieters can use this product just before eating meals to reduce the absorption of carbohydrate/starch calories."
- Ultra Block 2000 Plus C:
 - "[M]ay help to prohibit the absorption of fats in the stomach."
- Slender Quick 2000:
 - "Garcinia Cambogia [an ingredient in the product] blocks up to 70% of the conversion of carbohydrates into fat, thus helping to prevent added fat storage on the body."
 - "The extract [of Garcinia Cambogia] is effective in ...controlling appetite. It is a well-established fat burning agent and is known to be beneficial in weight management."
 - "Other benefits to your body are also associated with chromium supplementation. Two weight reduction benefits are: better blood sugar control which helps to better manage hunger; and secondly, some degree of muscle mass development, providing more fat burning capacity."

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your products to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act [21 U.S.C. § 343(a)(1) and 343 (r)(6)(B)]. It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded [21 U.S.C. § 331(a)]. It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded [21 U.S.C. § 331(k)].

This letter is not an all-inclusive review of your websites and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

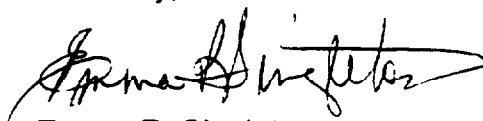
You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products [21 U.S.C. §§ 332 and 334].

Please advise this office, in writing within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective

actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. If you have scientific evidence that you believe substantiates the structure/function claims for Ultra Carbo Blocker 2000, Ultra Block 2000 Plus C, or Slender Quick 2000, you should include that in your response.

Your reply should be addressed to Shari H. Shambaugh, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District